

AMENDMENTS TO THE DRAWINGS

Please replace the Drawings filed December 29, 2004 (Figures 1-3; Sheets 1-3), with the Replacement Drawings (Figures 1-4; Sheets 1-4) submitted herewith.

Attachment: Replacement Sheets: 4

REMARKS

This Amendment, filed in reply to the Office Action dated April 15, 2010, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 4 and 5 are rejected. Claims 1-3 are objected to. Claims 2 and 3 are canceled herewith without prejudice or disclaimer. Claims 1, 4 and 5 are amended herewith solely to improve clarity and conciseness. Hence, no new matter is added by way of this amendment.

Entry and consideration of this amendment are respectfully requested.

Claim to Priority

Applicants thank the Examiner for acknowledging Applicants' claim to foreign priority, and for acknowledging receipt of certified copies of Applicants' foreign priority documents, namely JP 2003-74312 and JP 2002-227952.

Information Disclosure Statements

Applicants thank the Examiner for returning signed and initialed copies of the PTO Forms SB/08 that accompanied the Information Disclosure Statements filed April 4, 2005 and May 26, 2005.

Objections to the Specification

On page 2 of the Office Action, the Examiner objects to the specification as allegedly reciting nucleotide or amino acid sequences that are not identified by a unique sequence

identifier, *i.e.*, SEQ ID NO. Specifically, the Examiner points to the nucleotide and amino acid sequences recited on pages 7 and 12-16 of the specification as filed.

In response, Applicants submit herewith a revised copy of Table 2, designating the sequences recited therein with sequence identifiers. Specifically, Applicants respectfully point out that the various sequences recited in Table 2 refer to alternate codons, encoding the same or conservative amino acids, which may be used to produce an antibody with similar specificity to the 9F11 antibody. Consistent with M.P.E.P. §2422.03, which provides that “with respect to ‘conservatively modified variants thereof’ of a [nucleotide or amino acid] sequence, the sequences may be described as SEQ ID NO: X and “conservatively modified variants thereof,” Applicants herewith amend Table 2 to indicate that the sequences recited therein pertain to “SEQ ID NOs: 3 and 4, and conservatively modified variants thereof.” In addition, page 7 of the specification is amended herewith to recite unique sequence identifiers. Applicants respectfully submit that Applicants respectfully submit that the amendments overcome the objection.

Withdrawal of the objection is respectfully requested.

Objections to the Drawings

On page 2 of the Office Action, the Examiner objects to the Drawings as failing to include appropriate figure designations, *i.e.*, “Figure 1,” and because Figure 2 is allegedly missing.

In response to the first aspect of the objection, *i.e.*, that the claims do not contain the appropriate figure designations, Applicants submit herewith revised drawings designated by Figure number (e.g., “Figure 1”). Applicants respectfully submit that such overcomes this aspect of the objection.

In response to the second aspect of the objection, *i.e.*, that Figure 2 is missing, Applicants note that on December 24, 2004, three pages of drawings, corresponding to the Descriptions of Figures 1, 3 and 4 in the specification were submitted (labeled as Figures 1-3, respectively), with Figure 2 being inadvertently omitted. Applicants note that the corresponding International Stage Application, *i.e.*, PCT/JP2003/008306 (published as WO 04/003196), contains four Figures, including that which corresponds to the brief description of Figure 2 in the specification.

37 C.F.R. § 1.57(a) provides, in pertinent part, that if a portion of the specification or a drawing is inadvertently omitted from an Application, and the Application contains a claim under 37 C.F.R. § 1.78 to an International Application, that claim under 37 C.F.R. § 1.78 properly serves as an incorporation by reference of the prior-filed International Application as to the inadvertently omitted portions of the specification or drawings. In accordance with the provisions of 37 C.F.R. § 1.57(a), Applicants submit herewith a revised set of drawings, including omitted Figure 2, obviating the objection.

Withdrawal of the objection is respectfully requested.

Objections to the Claims

On page 3 of the Office Action, Claims 1-5 are objected to for the following reasons.

First, the Examiner objects to the language of Claim 1, asserting that “sequence No. 1” should be amended to recite “SEQ ID NO.,” and that the claim should recite that the antibody “binds” to activated cells, rather than it be “reactive” thereto.

Second, the Examiner objects to Claim 4 as allegedly containing a typographical error; the Examiner contends that Claim 4 should recite “[a] cell strain,” rather than “[a] cell stain.”

Third, the Examiner contends that Claim 5 should recite “the human IgM.”

Solely in the interest of advancing prosecution, and without acquiescing to the merits of the objection, Applicants herewith amend Claims 1, 4 and 5 to improve their overall clarity and conciseness. Applicants respectfully submit that the amendments overcome the objections.

Withdrawal of the objections is respectfully requested.

Claims 4-5 are Enabled Under 35 U.S.C. § 112, 1st Paragraph

1. On page 4 of the Office Action, Claims 4 and 5 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.

In making the rejection, the Examiner contends that the specification is not enabling for the subject matter of Claims 4 and 5 because (a) the specification does not set forth a reproducible method through which such an antibody or cell strain may be obtained, and (b) such an antibody or cell strain does not appear to be known and readily available to the public. Consequently, the Examiner asserts that a deposit may be required, in addition to an assurance that all restrictions on the deposited material will be irrevocably removed upon patent grant.

The Examiner has acknowledged the FERM BP-8379 deposit with the International Patent Organism Depositary, National Institute of Advanced Industrial Science and Technology, Japan, on May 8, 2003, as set forth on page 6 of the specification as filed. However, the Examiner contends that such, in itself, does not satisfy the enablement requirement of section 112, because Applicants have not made the requisite assurances that all restrictions on the deposit will be irrevocably removed upon issuance of a Patent.

Solely to advance prosecution, and without acquiescing to the merits of the rejection, Applicants submit herewith a Statement of Availability against the FERM BP-8379 cell line, obviating the rejection.

Withdrawal of the rejection is respectfully requested.

2. On page 6 of the Office Action, Claim 2 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.

In justifying the rejection, the Examiner contends that Claim 2 is directed to an “immunosuppressant” which comprises the claimed antibody; the Examiner takes the position that it would require undue experimentation for those of skill in the art to use the claimed antibody as an immunosuppressant. Although the Examiner acknowledges that the specification discloses that the presently claimed antibody is able to cause cytolysis of activated human lymphocytes, the Examiner asserts that there exists no evidence or data demonstrating that the antibody can cause immunosuppression in a subject, and that it would require undue experimentation to practice the subject matter of Claim 2 without such.

Solely in the interest of compacting prosecution, and without acquiescing to the merits of the rejection, Claim 2 is canceled herewith, without prejudice or disclaimer, mooted the rejection.

Withdrawal of the rejection is respectfully requested.

3. On page 6 of the Office Action, Claim 3 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.

In making the rejection, the Examiner acknowledges that the specification is enabling for a remedy to *treat* HIV. However, the Examiner takes the position that the presently claimed agent encompasses a vaccine for the prevention of HIV, and that the specification does not enable such a *preventative* vaccine. The Examiner cites to Haynes *et al.*, Burton *et al.*, Moore *et*

al. and Desrosiers *et al.* as allegedly evidencing unpredictability in the pertinent art to the extent that it would require undue experimentation to produce a preventative HIV vaccine.

Solely in the interest of compacting prosecution, and without acquiescing to the merits of the rejection, Claim 3 is canceled herewith, without prejudice or disclaimer, mooted the rejection.

Withdrawal of the rejection is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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CUSTOMER NUMBER

Date: July 15, 2010

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